UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,718	07/05/2001	Stefanie Sprunck	514413-3886	4044

7590 08/28/2002

William F. Lawrence, Esq.
c/o FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, NY 10151

EXAMINER	
SULLIVAN, DANIEL M	
ART UNIT	**PAPER NUMBER**
1636	10

DATE MAILED: 08/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/899,718	SPRUNCK ET AL.	
	Examiner	Art Unit	
	Daniel Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is a response to the Application filed July 5, 2001, claiming priority to German patent applications 10032379.0 filed July 6, 2000 and 10041861.9 filed August 26, 2000, and the Preliminary Amendment filed July 31, 2001. Claims 1-13, as originally filed, are pending in the application.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on July 6, 2000. It is noted, however, that applicant has not filed a certified copy of the 10041861.9 application as required by 35 U.S.C. 119(b).

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d) for German application 10041861.9, which papers have been placed of record in the file.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

Claim Objections

Claims 6, 11 and 12 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim (i.e. claims 4 or 6). See MPEP § 608.01(n). In the interest of compact prosecution, the claims have been examined on the merits according to their full scope. However, appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to a nucleic acid molecule with the function of a caryopsis-specific promoter comprising various nucleic acid sequences. As written, the claims read on a product of nature. This rejection can be traversed by amending the claim to indicate the hand of man. For example, amending claim 1 such that it is drawn to an isolated nucleic acid molecule.

Claims 13 and 14 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

As they depend from claim 1, part (d), the claims are drawn to a nucleic acid molecule with the function of a caryopsis-specific promoter comprising a sequence that hybridizes with at least one of the nucleotide sequences stated under part (a) or part (b); and as they depend from claim 1, part (e), the claims are drawn to a nucleic acid molecule with the function of a caryopsis-specific promoter comprising a sequence that has approximately 60-99% identity with one of the nucleic acid sequences stated under part (a). Given the broadest reasonable interpretation, the claims encompass any nucleic acid molecule that comprises a sequence with promoter activity that favors expression in the caryopsis by 2-fold (see specification page 10, first full paragraph) and meets the above sequence limitations. Furthermore, because the claim does not recite specific hybridization conditions, and the specification provides stringent hybridization conditions only as a preferred embodiment (see page 15, third full paragraph of the specification), the claim encompasses all caryopsis-specific promoters because, given sufficiently low stringency, the molecules of (a) or (b) will hybridize with any other DNA sequence. An adequate written description of a DNA requires more than a mere statement that it

is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. It is not sufficient to define DNA solely by its principal biological property, i.e. a caryopsis-specific promoter, because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any DNA with that biological property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, claiming all DNA's that achieve a result without defining what means will do is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). With respect to the method claims, adequate description of the methods first requires an adequate description of the materials, i.e. specific DNA sequences, which provide the means for practicing the invention.

In view of these considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of *any* and *all* DNAs with caryopsis-specific promoter activity and having the indicated similarity to the disclosed sequence. Therefore, only the described sequences meet the written description provision of 35 U.S.C. §112, first paragraph.

Claims 14 and 16 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to processes wherein the nucleic

acid molecule of claim 1 are used to suppress expression of genes in the caryopsis. The disclosure provides no more than a broad statement that the disclosed nucleic acids can be used for the purpose of caryopsis-specific gene suppression (see page 20, final paragraph and page 24, second full paragraph) and that the promoters can be used to express antisense RNA or a ribozyme without a teaching as to the purpose of expressing these molecules. The disclosure does not provide any guidance with regard to how caryopsis-specific gene suppression can be achieved, nor does it provide any examples of caryopsis-specific gene suppression. In view of these considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention. Therefore, the claims fail to meet the written description provision of 35 U.S.C. §112, first paragraph.

Claims 14 and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As described above, the claims are very broadly drawn to a means of suppressing gene expression in the caryopsis using the nucleic acid molecule of claim 1, and in the case of claim 16 said nucleic acid molecule is stably integrated into the genome of a plant. The disclosure provides a nucleic acid sequence for a caryopsis-specific promoter and a broad statement that the promoter can be used to suppress gene expression in the caryopsis but no working examples. The disclosure also provides that the promoter can be used to express antisense RNA or ribozyme. Although the prior art teaches that antisense RNA and ribozymes can be used to suppress gene expression, these methods require detailed knowledge of the target

molecule and empirical experimentation to identify an effective inhibitory molecule. In an article published well after the effective filing date of the instant application, Far et al. (*Bioinformatics* (2001) 17:1058-1061) teach that the "successful use of [antisense oligonucleotides] to suppress gene expression is somewhat limited since only a small portion of all possible antisense species against a given target sequence shows efficacy..." (page 1058, column 1, first paragraph of the introduction). Far also teaches that in spite of a considerable amount of empirical data on the use of antisense oligonucleotides, the work "does not seem to be reflected by the knowledge on the biophysical and biochemical level of the action of [antisense oligonucleotides] nor by the knowledge about the rules that govern the relationship between specific sequences of [antisense oligonucleotides], the influence of the target structure, the annealing *in vitro*, and the efficacy *in vivo*" (beginning on page 1058, column 1, third from final line through the fourth line of column 2). Finally, Far teaches, "the effectiveness of [antisense oligonucleotides] is strongly dependent on local target RNA structures, on chemical properties and sequences of the [antisense oligonucleotide] species, and on the characteristics of the biological system of interest including the metabolic properties of the target RNA and the gene product, respectively" (page 1058, column 2, first full paragraph). Because these teachings refer to the state of the art with regard to predictability of efficacy based on analysis of sequence data, they are equally true for any strategy that relies on *in vivo* hybridization of nucleic acid sequences. Thus, Far teaches that in spite of relatively advanced status of the art, the success or failure of antisense technology in inhibiting expression of any given gene is highly unpredictable. Given this unpredictability, the breadth of the claims, which encompass inhibition of expression of any and all genes in the caryopsis, and the failure of the specification to provide any working examples of how the

invention can be used according to the claims, one of ordinary skill in the art would not be able to practice the claimed invention without significant empirical experimentation to develop an efficacious inhibitor for each and every gene. This would place an undue burden on one seeking to practice the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, and all claims depending from claim 1, are drawn to a nucleic acid molecule with a function of a caryopsis-specific promoter, which comprises, according to part (c), a sequence which has approximately 60-99%, or approximately 75-99%, or approximately 95-99% identity with the nucleic acid sequence stated under (a). A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex*

parte Steigewald, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation approximately 60-99%, and the claim also recites 95-99%, which is the narrower statement of the range/limitation.

In addition, claims 13 and 14 provide for the use of a nucleic acid molecule, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Visser et al. (1991) *Plant Mol. Biol.* 17:691-699.

Claim 1 is drawn to a nucleic acid molecule with the function of a caryopsis-specific promoter, which nucleic acid molecule comprises a sequence that hybridizes with at least one of the nucleotide sequences set forth as SEQ ID No:1-8 in the instant application, and claim 2 is drawn to the nucleic acid molecule of claim 1 that is a promoter active in plants. As argued above, any caryopsis specific promoter would read on the claims. Therefore, the potato GBSS

promoter described by Visser in the second full paragraph of the first column on page 692 and in the reference cited therein meets the limitations of the claim.

Claim 3 is drawn to an expression cassette comprising a nucleic acid molecule as claimed in claim 1; claim 4 is drawn to a vector comprising the nucleic acid of claim 1 or the expression cassette of claim 3; and claim 5 limits the vector of claim 4 which is suitable for transforming plant cells. On page 692, in the section entitled *Construction of a chimaeric granule-bound starch synthase-GUS gene*, Visser teaches the plasmid pPGB-1, a vector suitable for transforming plant cells that comprises an expression cassette comprising a nucleic acid molecule as claimed in claim 1. pPGB-1 is the same as the vector taught in the instant application.

Claim 6 is drawn to a host cell genetically modified with the nucleic acid molecule of claim 1, the expression cassette of claim 3 or the vector of claim 4. Claim 7 limits the host cell of claim 6 to a pro- or eukaryotic cell and claim 8 limits the host cell of claim 6 to a plant cell. Also in the section entitled *Construction of a chimaeric granule-bound starch synthase-GUS gene*, Visser further teaches introducing pPGB-1 into competent *Agrobacterium tumeficiens* to produce the prokaryotic host cell of claims 6 and 7, and in the section entitled *Plant transformation and tissue culture* beginning on page 692, Visser teaches transformation of tuber slices or stem explants to produce the eukaryotic plant cell of claims 6, 7 and 8.

Claim 9 is drawn to a plant comprising plant cells as claimed in claim 8 and claim 10 is drawn to propagation material or harvested material from plants as claimed in claim 9. In the section *Plant transformation and tissue culture*, Visser teaches transgenic potato plants obtained from transformed tuber and stem explants, tuber and stem explants as propagation material and

harvested material such as tissue extracts (see especially *Preparation of tissue extracts* on page 693, column 1) from plants transformed with pPGB-1. Therefore, the teachings of Visser anticipate the claims.

Claims 11 and 12 are drawn to a method of generating transgenic plant cells as claimed in claim 8 and transgenic plants as claimed in claim 9, respectively, wherein plant cells, plant tissue, plant parts or protoplasts are transformed with a nucleic acid molecule as claimed in claim 1, a vector as claimed in claim 4, an expression cassette as claimed in claim 3 or with a host cell as claimed in claim 6, and the transformed plant cells, plant tissues, plant parts or protoplasts are grown in a growth medium. Claim 12 includes the additional process step of regenerating intact plants from the transformed material. As described above, Visser teaches methods of generating transgenic plants and plant cells comprising the pPGB-1 expression vector, which meet the limitations of the claims.

Claim 15 is drawn to a method for caryopsis-specific gene expression in plants, wherein a nucleic acid molecule as claimed in claim 1 is stably integrated into the genome of a pant cell, and the plant is regenerated from said plant cell. The data presented in Table 2, on page 694, indicate that the method of Visser described above provides caryopsis-specific gene expression in plants, therefore the method of Visser meets the limitations of the claim.

The nucleic acid molecule, expression cassette, vector, host cell, transgenic plant, material, and methods taught by Visser are the same as those taught in the instant application, therefore the limitations of the claims are met by Visser.

Claims 1-8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Steege et al. (1992) *Plant Mol. Biol.* 20: 19-30.

The limitations of the claims are recited above. Steege teaches a nucleic acid with the function of a caryopsis-specific promoter, the potato GBSS promoter, an expression cassette comprising the promoter and a vector, suitable for transforming plant cells, comprising the expression cassette (see especially Figure 1 on page 21). Steege also teaches bacterial, *A. rhizogenes*, and plant cells transformed with the vector, and a method of generating a transgenic plant cell wherein plant tissue is transformed with the above vector and the transformation product is grown in a growth medium (see especially "Agrobacterium rhizogenes *transformation*" on page 21). The nucleic acid molecule, expression cassette, vector, host cell and methods taught by Steege are the same as those taught in the instant application, therefore the limitations of the claims are met by Steege.

Allowable Subject Matter

None of the claims are allowable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on 703-305-1998. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
August 25, 2002

JAMES KETTER
PRIMARY EXAMINER